Fariba Mohseni et al., Biochem Pharmacol (Los Angel) 2017, 6.2 (Suppl)
DOI: 10.4172/2167-0501-C1-007

Universal real-time PCR assay for quantitation of residual host cell DNA in human recombinant protein based on CHO available in Iranian market

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Statement of the Problem: Chinese hamster ovary (CHO) cells are the host cell for manufacturing of human recombinant proteins drugs in the biopharmaceutical industry. Host cell DNA is an impurity of such manufacturing process and must be controlled and monitored in order to ensure drug purity and safety. Real-time quantitative PCR is a precise method for quantification of residual host cell DNA in therapeutic protein preparations. In the present study, 18 different types of drugs including erythropoietin, interferon beta 1-a, Follicle Stimulating Hormone (FSH), recombinant factor VII which were available in Iranian market and imported or produced by Iranian companies were examined and the amounts of residual host cell DNA were measured by means of real-time PCR.

Materials & Methods: Real-time PCR kit purchased and applied according to the manufacturer instructions, real time PCR instrument, micro-centrifuge and 2 mL microfuge tube were used. Following cycling conditions: 10 min at 95°C, one cycle followed by 50 cycles each consisting of 40 s at 95°C, 30 s at 60°C and30 s at 72°C was used.

Results: The mean amount of residual DNA in Iranian manufactured products was 2.14 pg/ml while the amount of residual DNA in imported product was 3.05×10^{-7} pg/ml which was lower than World Health Organization and U.S. Food and Drug Administration guidelines (10 ng/dose).

Discussion: The assay was demonstrated to be specific, precise, and accurate to quantitate residual *E. coli* DNA in the linear and quantitative range from 1 pg/mL to 100 pg/mL.

Biography

Fariba Mohseni has 12 years experiences in adult endocrinology and medical fields and is working on the effects of gene-base impurities in recombinant therapeutic proteins recently. She has published 11 articles in scientific journals.

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